



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0411; FRL-9990-59]

Certain New Chemicals; Receipt and Status Information for December 2018

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to make information publicly available and to publish information in the **Federal Register** pertaining to submissions under TSCA Section 5, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from 12/01/2018 to 12/31/2018.

DATES: Comments identified by the specific case number provided in this document must be received on or before *[insert date 30 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0411, and the specific case number for the chemical substance related to your comment, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider

to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jim Rahai, Information Management Division (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8593; email address: rahai.jim@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from 12/01/2018 to 12/31/2018. The Agency is providing notice of receipt of PMNs, SNUNs and MCANs (including amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new

chemical substance; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its web site about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notice>. This information is updated on a weekly basis.

B. What is the Agency's authority for taking this action?

Under the TSCA, 15 U.S.C. 2601 *et seq.*, a chemical substance may be either an “existing” chemical substance or a “new” chemical substance. Any chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a “new chemical substance,” while a chemical substance that is listed on the TSCA Inventory is classified as an “existing chemical substance.” (See TSCA section 3(11).) For more information about the TSCA Inventory go to: *<https://www.epa.gov/tsca-inventory>*.

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN or SNUN, as appropriate, before initiating the activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3).

TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical

substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a)(2), for “test marketing” purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to:

<http://www.epa.gov/oppt/newchemicals>.

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the **Federal Register** certain information, including notice of receipt of a PMN/SNUN/MCAN (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

This action provides information that is directed to the public in general.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

E. What should I consider as I prepare my comments for EPA?

1. *Submitting confidential business information (CBI).* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain

the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Status Reports

In the past, EPA has published individual notices reflecting the status of TSCA section 5 filings received, pending or concluded. In 1995, the Agency modified its approach and streamlined the information published in the **Federal Register** after providing notice of such changes to the public and an opportunity to comment (See the **Federal Register** of May 12, 1995 (60 FR 25798) (FRL-4942-7). Since the passage of the Lautenberg amendments to TSCA in 2016, public interest in information on the status of section 5 cases under EPA review and, in particular, the final determination of such cases, has increased. In an effort to be responsive to the regulated community, the users of this information, and the general public, to comply with the requirements of TSCA, to conserve EPA resources and to streamline the process and make it more timely, EPA is providing information on its web site about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices>. This information is updated on a weekly basis.

III. Receipt Reports

For the PMN/SNUN/MCANs received by EPA during this period, Table I provides the following information (to the extent that such information is not subject to a CBI claim) on the

notices received by EPA during this period: The EPA case number assigned to the notice that indicates whether the submission is an initial submission, or an amendment, a notation of which version was received, the date the notice was received by EPA, the submitting manufacturer (i.e., domestic producer or importer), the potential uses identified by the manufacturer in the notice, and the chemical substance identity.

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter “A” (e.g. P-18-1234A). The version column designates submissions in sequence as “1”, “2”, “3”, etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier versions were rejected as incomplete or invalid submissions. Note also that future versions of the following tables may adjust slightly as the Agency works to automate population of the data in the tables.

Table I. – PMN/SNUN/MCANs Received from 12/01/2018 to 12/31/2018

| Case No. | Version | Received Date | Manufacturer | Use | Chemical Substance |
|-----------------|----------------|----------------------|--------------------------------|---|---|
| J-19-0011 | 1 | 12/23/2018 | Danisco US, Inc. | (G) Production of a chemical substance | (G) Genetically modified microorganism for the production of a chemical substance |
| P-19-0011 | 4 | 12/20/2018 | Shin etsu Silicones of America | (G) Additive to the EPDM rubber compounds | (G) Polysulfides, bis[3-(trialkoxysilyl)propyl] |
| P-19-0030 | 2 | 12/18/2018 | CBI | (G) Water Systems | (G) Triethanolamine modified Phosphinocarboxylate |

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|-----------|---|------------|----------------------------|---|--|
| | | | | | s, sodium salts |
| P-19-0031 | 2 | 12/28/2018 | CBI | (S) Curing agent for epoxy coating systems | (G) Phenol, 4,4'-(1-methylethylidene)bis-, polymer with formaldehyde, 2-(chloromethyl)oxirane, alpha-hydro-omega-hydroxypoly(oxy-1,2-ethanediyl), and polyamines |
| P-19-0034 | 1 | 12/6/2018 | CBI | (G) Contained use as a component of tires | (G) Metal, bis(2,4-pentanedionato-kO2,kO4)-, (T-4)- |
| P-19-0035 | 3 | 12/10/2018 | Firmenich, Inc. | (G) Fragrance | (S) Acetamide, 2-(4-methylphenoxy)-N-1H-pyrazol-3-yl-N-(2-thienylmethyl)- |
| P-19-0036 | 1 | 12/10/2018 | Ethox Chemicals, LLC | (S) As an additive to polymers for improvement in gas barrier performance | (S) 1,4-Benzenedicarboxylic acid, 1,4-bis(2-phenoxyethyl) ester |
| P-19-0037 | 1 | 12/11/2018 | CBI | (G) Chemical intermediate | (G) D-Glucaric acid, mixed alkali metal salt |
| P-19-0038 | 2 | 12/14/2018 | Allan Chemical Corporation | (S) Ink carrier for the ceramic industries | (S) Fatty acids, coco, iso-Bu esters |
| P-19-0040 | 1 | 12/20/2018 | CBI | (G) Intermediate | (G) Alkyl bis(dialkylamino alkyl) amide |
| P-19-0041 | 1 | 12/20/2018 | CBI | (G) Oil water separation | (G) Alkyl diester, polymer with (dialkylamino alkyl) amine and bis(halogenated alkyl) ether |
| P-19-0042 | 1 | 12/20/2018 | CBI | (G) Oil water separation | (G) Alkyl diester, polymer with (dialkylamino alkyl) amine and bis(halogenated alkyl) ether |
| P-19-0043 | 1 | 12/20/2018 | CBI | (G) Oil water separation | (G) Alkyl dicarboxylic acid, polymer with |

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|------------|---|------------|-------------------------------|--|---|
| | | | | | (dialkylamino alkyl) amine and bis(halogenated alkyl) ether |
| P-19-0044 | 1 | 12/20/2018 | CBI | (G) Oil water separation | (G) Alkyl bis(dialkylamino alkyl) amide polymer with bis(halogenated alkyl) ether |
| P-19-0045 | 1 | 12/21/2018 | CBI | (G) Component of textile coating | (G) Non-metal tetrakis (hydroxyalkyl)-, halide, polymer with amide oxidized |
| SN-19-0002 | 2 | 12/20/2018 | Otsuka Chemical America, Inc. | (G) Friction and wear stabilizer in certain solid composite articles | (G) Potassium Titanate |

In Table II. of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs received by EPA during this period: The EPA case number assigned to the NOC including whether the submission was an initial or amended submission, the date the NOC was received by EPA, the date of commencement provided by the submitter in the NOC, a notation of the type of amendment (e.g., amendment to generic name, specific name, technical contact information, etc.) and chemical substance identity.

Table II. – NOCs Received From 12/01/2018 to 12/31/2018

| Case No. | Received Date | Commencement Date | If Amendment, Type of Amendment | Chemical Substance |
|-----------|---------------|-------------------|---------------------------------|--|
| J-16-0021 | 12/04/2018 | 12/04/2018 | | (G) Modified trichoderma reesei |
| J-18-0026 | 12/21/2018 | 11/30/2018 | | (G) Biopolymer producing modified microorganism(s), with chromosomally-borne modifications |
| J-18-0027 | 12/21/2018 | 12/07/2018 | | (G) Biopolymer producing modified microorganism(s), with chromosomally-borne modifications |

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|------------|------------|------------|---|--|
| J-18-0044 | 12/21/2018 | 11/26/2018 | | (S) <i>Saccharomyces cerevisiae</i> NE095 |
| P-12-0168 | 12/13/2018 | 12/07/2018 | | (S) 1,3,5-Triazine-2,4,6-triamine, N-(4,6-diamino-1,3,5-triazin-2-yl)- |
| P-16-0150 | 12/20/2018 | 11/29/2018 | | (G) Chlorofluorocarbon |
| P-16-0173A | 12/20/2018 | 06/06/2016 | Updated CBI substantiation for importing site and update to generic chemical name | (G) Aminoalkyl alaninate sodium salt (1:1), polymer with alkyl diol, dialkyl-alkanediol, alkyl dioic acid, alkyl diol, polyol, cycloaliphatic diisocyanate, polyalkylene glycol mono-alkyl ether-blocked |
| P-16-0221 | 12/14/2018 | 12/13/2018 | | (G) Fluorinated organopolysilazane |
| P-17-0330 | 12/11/2018 | 12/03/2018 | | (G) Hexanedioic acid, polymer with trifunctional polyol, 1,1'-methylenebis [isocyanatobenzene], and 2,2'-oxybis [ethanol] |
| P-17-0332 | 12/14/2018 | 11/20/2018 | | (G) Benzenesulfonic acid, (alkenediyl)bis[[[(hydroxyalkyl)amino]-(phenylamino)-triazin-2-yl]amino]-, N-(hydroxyalkyl) derivs., salts, |
| P-18-0002 | 12/05/2018 | 12/05/2018 | | (S) Phosphinic acid, P,P-diethyl-, sodium salt (1:1) |
| P-18-0147 | 12/13/2018 | 11/29/2018 | | (G) Phenol, 4-ethenyl-, 1-substituted, polymer with 1-(1,1-substituted)-4-ethenylbenzene and ethenylbenzene, 2, 2'-(1,2-diazenediyl)bis[2-substituted]-initiated, hydrolyzed |
| P-18-0212 | 12/11/2018 | 12/07/2018 | | (G) Substituted carbomonocycle, polymer with alkyl alkenoate, alkenyl substituted carbomonocycle, substituted alkanediol, heteropolycycle, alkylene glycol and alkenoic acid, compd. with alkylamino alkanol |
| P-18-0261 | 12/06/2018 | 12/05/2018 | | (G) Metal, alkylcarboxylate oxo complexes |

| | | | | |
|-----------|------------|------------|--|--|
| P-18-0279 | 12/17/2018 | 12/14/2018 | | (G) Substituted heteromonocycle, polymer with substituted alkanediol and diisocyanate substituted carbomonocycle, alkylene glycol acrylate-blocked |
|-----------|------------|------------|--|--|

In Table III. of this unit, EPA provides the following information (to the extent such information is not subject to a CBI claim) on the test information received by EPA during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

Table III. – Test Information Received from 12/01/2018 to 12/31/2018

| Case No. | Received Date | Type of Test Information | Chemical Substance |
|-----------------|----------------------|---|--|
| P-00-0281 | 12/4/2018 | Fish Acute Toxicity (OECD 203) Invertebrate Acute Toxicity (Fathead minnows), Algae Toxicity (Raphidocelis subcapitata) | (G) Alkarylsulfonic acid, sodium salts |
| SN-17-0011 | 12/4/2018 | Whole Body (Inhalation) 2 Generation Reproductive Toxicity Study and Work Place Air Monitoring and Exposure Modeling Study | (G) Polyfluorohydrocarbon |
| P-87-1436 | 12/6/2018 | QSAR Assessment Report on Vinyl Laurate; Skin Sensitization: Local Lymph Node Assay (OECD TG 429); Repeated Dose 90-Day Oral Toxicity in Rodents (OECD TG 408); Repeated Dose Toxicity and Repro/Devel Toxicity Screening (OECD TG 422); Chromosome Aberration Test (OECD TG 473); Gene Mutation Assay (OECD TG 476); Micronucleus Test (OECD TG 474); Prenatal Developmental Toxicity Study (OECD TG 414); Aquatic Toxicity – Daphnia (OECD TG 202); Aquatic Toxicity – Daphnia Reproductive (OECD TG 211); Aquatic Toxicity – Algal Growth (OECD TG 201); Ready Biodegradability (OECD TG 301); Dermal Irritation/Corrosion (OECD TG 404); Bacterial Reverse Mutation Assay – Ames Test (OECD 471); Fish Acute Toxicity (OECD TG 203); Activated Sludge Test (OECD TG 209); Acute Oral Toxicity (OECD | (S) Dodecanoic acid, ethenyl ester |

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|-----------|------------|---|--|
| | | TG 401); Acute Eye Irritation (OECD TG 405); Acute Dermal Toxicity (OECD TG 402). Note: There are no additional processing and use requests beyond the original PMN, except for allowing our site limited use as a monomer in polymer production. Added commentary on EPA Risk Assessment | |
| P-11-0483 | 12/7/2018 | Routine/Annual Testing and Reporting: Certifications of Analysis | (G) Alkyl thiol |
| P-11-0484 | 12/7/2018 | Routine/Annual Testing and Reporting: Certifications of Analysis | (G) Alkyl sulfate salt |
| P-11-0487 | 12/7/2018 | Routine/Annual Testing and Reporting: Certifications of Analysis | (G) Alkyl polyamide |
| P-11-0527 | 12/7/2018 | Routine/Annual Testing and Reporting: Certifications of Analysis | (G) Substituted fluoroalkane |
| P-11-0528 | 12/7/2018 | Routine/Annual Testing and Reporting: Certifications of Analysis | (G) Fluorinated thiol |
| P-11-0529 | 12/7/2018 | Routine/Annual Testing and Reporting: Certifications of Analysis | (G) Fluorinated monomer |
| P-11-0530 | 12/7/2018 | Routine/Annual Testing and Reporting: Certifications of Analysis | (G) Fluoropolyacrylamide |
| P-11-0532 | 12/7/2018 | Routine/Annual Testing and Reporting: Certifications of Analysis | (G) Polyfluoroalkyl amine |
| P-11-0533 | 12/7/2018 | Routine/Annual Testing and Reporting: Certifications of Analysis | (G) Non-ionic fluorosurfactant |
| P-11-0534 | 12/7/2018 | Routine/Annual Testing and Reporting: Certifications of Analysis | (G) Anionic fluorosurfactant |
| P-11-0543 | 12/7/2018 | Routine/Annual Testing and Reporting: Certifications of Analysis | (G) Polyfluorinated alkyl quaternary amine chloride |
| P-17-0115 | 12/11/2018 | Skin Sensitization: Local Lymph Node Assay (OECD Test Guideline 429) | (G) Aminoalkyl alkoxysilane |
| P-17-0337 | 12/12/2018 | Industrial Hygiene Monitoring Report | (S) Aluminum cobalt lithium nickel oxide |
| P-18-0382 | 12/10/2018 | Consumer Exposure Data | G) Xanthylum, bis[dicarboxycyclic]sulfonylamino-alkylcyclicamino-disulfo-sulfocyclic-, inner salt, monocationic salt |

If you are interested in information that is not included in these tables, you may contact

EPA's technical information contact or general information contact as described under **FOR**

FURTHER INFORMATION CONTACT to access additional non-CBI information that may be available.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: March 7, 2019.

Pamela Myrick,

Director, Information Management Division, Office of Pollution Prevention and Toxics.

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